BIOFREEZE- menthol spray
Performance Health LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Biofreeze Spray

Drug Facts

Active Ingredients:

Menthol 10.5%

Purpose:

Cooling Pain Relief

Uses

Temporary relief from minor aches and pains of sore muscles and joints associated with: arthritis backache strains and sprains

Warnings

For external use only.

Flammable:

Keep away from excessive heat or open flame.

Contents Under Pressure. Do Not Puncture Or Incinerate Do Not Store At Temperature Above 120°F

Ask a Doctor Before using If You have:

Sensitive skin

When Using This Product

Avoid contact with the eyes or mucous membranes; Do not apply to wounds or damaged skin; Do not use with other ointments, creams, sprays or liniments; Do not apply to irritated skin or if excessive irritation develops; Do not bandage; Wash hands after use with cool water; Do not use with heating pad or device; Store in a cool dry place

Stop Use And Ask A Doctor If:

Condition worsens, or if symptoms persist for more than 7 days, or clear up and recur

If pregnant or breast-feeding:

Ask a health professional before use

Keep out of reach of children:

If accidentally ingested, get medical help or contact a Poison Control Center immediately

Directions:

Adults and children 12 years of age and older: Spray on to the affected areas not more than 4 times daily; massage not necessary
Children under 12 years of age: Consult physician

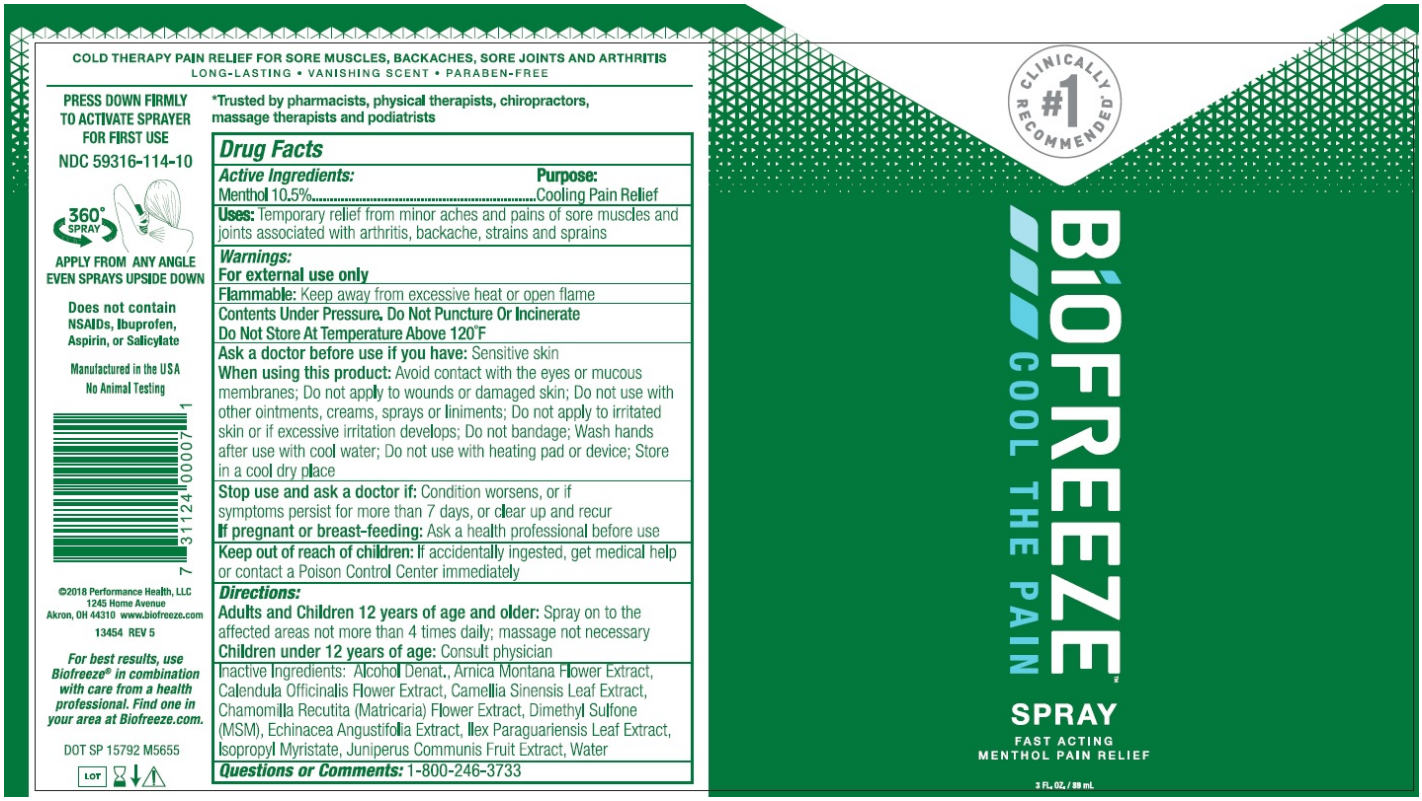
Inactive Ingredients

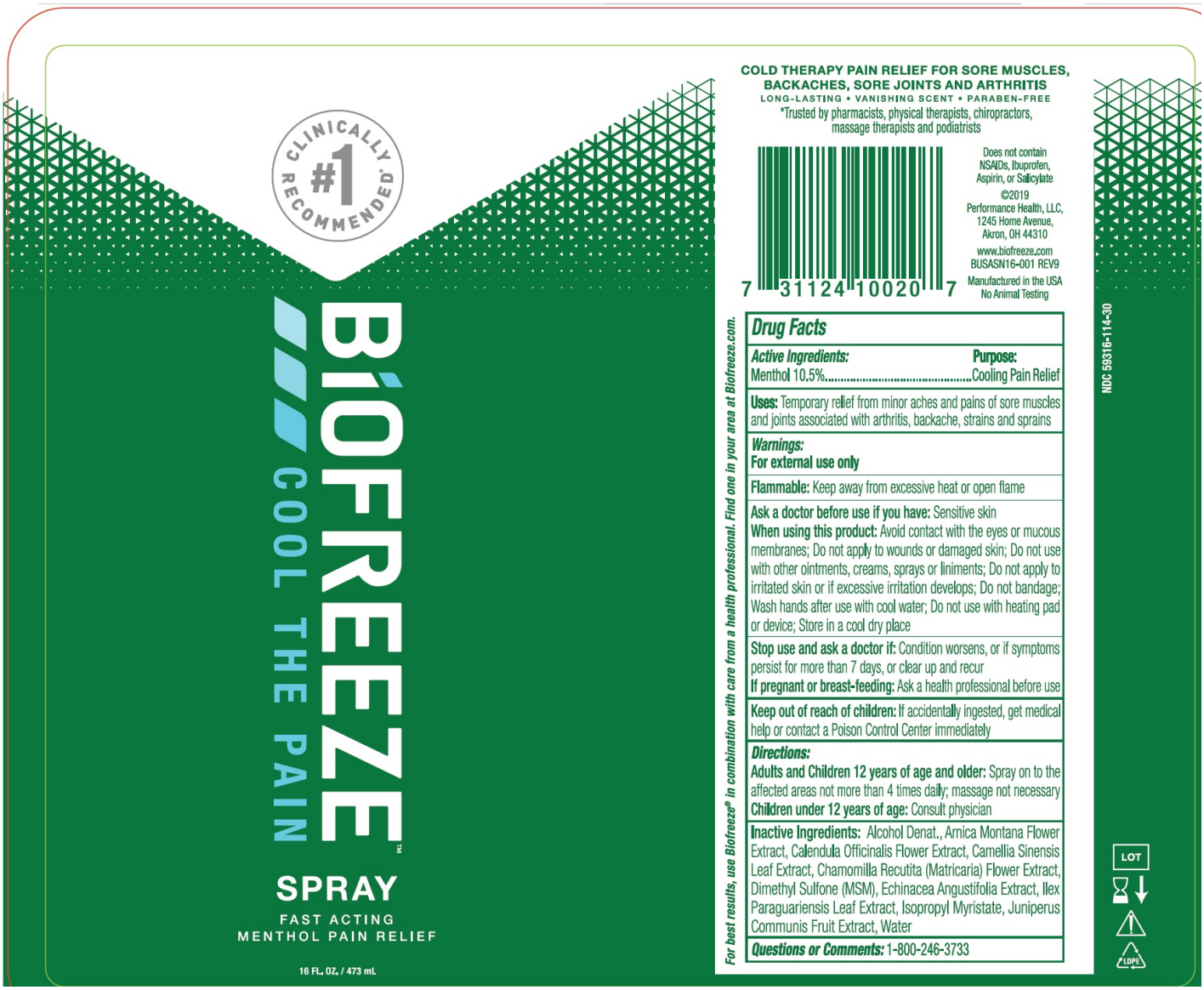
Alcohol Denat., Arnica Montana Flower Extract, Calendula Officinalis Flower Extract, Camellia Sinensis Leaf Extract, Chamomilla Recutita (Matricaria) Flower Extract, Dimethyl Sulfone (MSM), Echinacea Angustifolia Extract, Ilex Paraguariensis Leaf Extract, Isopropyl Myristate, Juniperus Communis Fruit Extract, Water

Questions or Comments:

1-800-246-3733

Package Labeling:





BIOFREEZE

menthol spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59316-114
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	105 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ARNICA MONTANA (UNII: O80TY208ZW)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	

CHAMOMILE (UNII: FGL3685T2X)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
ECHINACEA, UNSPECIFIED (UNII: 4N9P6CC1DX)	
ALCOHOL (UNII: 3K9958V90M)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
JUNIPERUS COMMUNIS WHOLE (UNII: 464910T5N9)	
BERRY (UNII: FV3431923Z)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59316-114-10	89 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/19/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	09/19/2016	

Labeler - Performance Health LLC (794324061)

Revised: 6/2019 Performance Health LLC